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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,573

11/28/2003

Mark William James Ferguson

39-289

4956

23117

7590

10/11/2006

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/722,573	Applicant(s) FERGUSON, MARK WILLIAM JAMES	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/029,098.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/28/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's preliminary amendment filed on 28 November 2003 is acknowledged and entered. Following the amendment, the original claims 1-24 are canceled, and the new claims 25-29 are added.

Currently, claims 25-29 are pending and under consideration.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 11/28/03 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. applications 09/459,979 filed on 12/14/99, and 09/029,098 filed on 5/13/98, which is acknowledged.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite for the recitation "a site of wounding", which does not refer to the chronic wound of claim 25, from which the claim is dependent.

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Claim 27 recites the limitation "wherein between 7,500 and 15,000 IU IFN- γ " in lines 1-2. There is insufficient antecedent basis for this limitation in the claim because claim 25 refers only to "stimulators of IFN- γ , not IFN- γ ."

Claim 28 is indefinite because it is unclear what "a partially modified form of IFN- γ " refers to, and whether it is sequence or chemical modifications, or something else, and the specification does not clearly define such. The metes and bounds of the claim, therefore, cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 25-29 are directed to a method for promoting the healing of a *chronic wound* using a stimulator of IFN- γ . However, the experiment results provided in the specification indicate otherwise. The specification discloses that according to the present invention there is provided an *inhibitor* of IFN- γ for use in promoting the healing of wounds and fibrotic disorders with reduced scarring (page 2, the second paragraph, page 3, the third paragraph). Further, the specification teaches that the inhibitor of IFN- γ may be used in conjunction with a composition for promoting the healing of chronic wounds (page 4, the second paragraph), indicating the use of the inhibitor of IFN- γ for chronic wounds, and contradicting the claimed invention. Assuming the claimed method for promoting the healing of a chronic wound with IFN- γ worked, according

to the teachings in the present specification, an inhibitor of IFN- γ , such as an anti-IFN- γ antibody could be used in conjunction with IFN- γ for promoting the healing of chronic wounds, which would be completely contradictory.

Furthermore, in the working example disclosed in the specification (pages 7-10), the experimental results show that *anti*-IFN- γ treatment is anti-scarring, improving the quality of dermal architecture (page 9, line 1), whereas all the IFN- γ -treated wounds showed increased inflammation and angiogenesis in a dose-dependent manner, and worse than control wounds (page 9, the second paragraph). By 70 and 120 days, high dose IFN- γ -treated wounds showed *marked scarring and residual inflammation*, the greater the dose of IFN- γ , the greater scarring (page 9, the third paragraph), which does not suggest a positive role of IFN- γ in *promoting* the healing of wounds. Based on such results, the specification indicates that the experiments also show that treatment of a site with IFN- γ actually promotes the deposition of collagen and healing with increased scarring and therefore *may be* used to promote the healing of chronic wounds (page 5, the first paragraph). Note, there is no working example of treating *chronic* wound with IFN- γ in the specification. Clearly, the present invention is based on extrapolation of the results from acute wounds. Such is not sufficient to enable the claimed invention because the result of treating *chronic* wound with IFN- γ is not predictable as the art has established that the wound healing is extremely complicated. For example, Goppelt et al. (US 2006/0014158 A1) teaches that the wound healing process in the skin is enormous complex, and involve the chronologically sequential, partially overlapping phases (page 1, [0002]), and that the correct interplay of the numerous growth factors is influenced by a multiplicity of factors, such as the quantity, the spatial and chronological distribution, and the combination of growth factors, this approach turns out to be extremely complicated (page 1, [0004]). As another example, Carpenter et al. (US 2006/0024357 A1) teaches that because chronic wounds heal by slightly different mechanisms than those of acute wounds, experimentation with growth factors should be investigated (page 3, [0023]). As another example, Schultz et al. (Wound Repair and Regeneration, March-April 2003, 11 (2) Supplement, pp. 1-28) teaches that the healing process in acute wounds has been extensively studied and the knowledge derived from these studies has often been extrapolated to the care of chronic wounds, on the assumption that nonhealing chronic wounds were simply

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aberrations of the normal tissue repair process; that however, this approach is less than satisfactory, as the chronic wound healing process differs in many important respects from that ~~seen in acute wounds, and that is important, therefore, to understand the molecular events that~~ are involved in the wound healing process in order to select the most appropriate intervention (the abstract). As such, the effect of treatment for chronic wounds would not be predictable from that for acute wounds, and the effect of IFN- γ on promoting the healing of a chronic wound would not be predictable from the instant disclosure because no chronic wound is ever treated with IFN- γ or a stimulator thereof. Therefore, a skilled artisan would not know how to use the present invention for the purpose of promoting the healing of a chronic wound. Undue experimentation would be required prior to using the claimed invention.

Due to the large quantity of experimentation necessary to determine the actual role of IFN- γ in promoting the healing of a *chronic* wound, the absence of working examples directed to same, the presence of working examples supporting the otherwise, the extremely complex nature of the invention, the lack of predictability, and the state of the prior art establishing that chronic wounds healing differs from that of acute wounds, and experimentation is necessary, undue experimentation would be required of the skilled artisan to use the claimed invention.

Claims 25, 26 and 29 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25, 26 and 29 are directed to a method for promoting the healing of a chronic wound using *a stimulator* of IFN- γ . However, the specification merely discloses IFN- γ for the treatment of wound, and no other stimulator of IFN- γ meeting the limitations of the claims is identified or particularly described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of IFN- γ , the skilled artisan cannot envision the detailed chemical structure of the encompassed stimulators of IFN- γ , and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, no stimulator of IFN- γ except IFN- γ meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art:

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Goppelt et al. (US 2006/0014158 A1) teaches the use of FGF-BP for treating wound healing disturbances (the abstract). Additionally, Goppelt teaches that IL-1, TNF and IFN- γ exert an effect on the secretion of the extracellular matrix components (page 1, the last sentence of [0002]), indicating that IFN- γ may have a role in wound healing.

Conclusion:

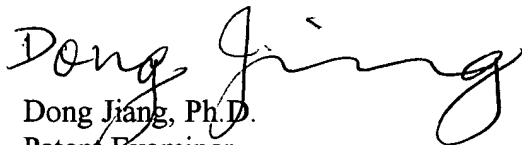
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in cursive script that reads "Dong Jiang".

Dong Jiang, Ph.D.
Patent Examiner

AU1646

9/28/06